

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Barry Davison on June 25, 2009.

The application has been amended as follows:

In the claims:

In claim 1, line 2, after the phrase "SEQ ID NOS: 14", the word "and" was replaced by a comma.

In claim 8, line 2, after the phrase "SEQ ID NOS: 15", the word "and" was replaced by a comma.

In claim 18, line 3, after the phrase "SEQ ID NOS: 14", the word "and" was replaced by a comma.

In claim 18, line 16, after the phrase "SEQ ID NOS: 15", the word "and" was replaced by a comma.

Claim 19. The pharmaceutical composition of claim 18, wherein the agent is the isolated polypeptide comprising the amino acid sequence selected from the group consisting of SEQ ID NOS: 14, ~~and~~ 19-28, and the fragments thereof ~~of about 50-70 contiguous residues in length.~~

Claim 20. The pharmaceutical composition of claim 18, wherein the agent is the combination of the isolated polypeptide comprising the amino acid sequence selected from the group consisting of SEQ ID NOS: 14, and 19-28, and the fragments thereof ~~of about 50-70 contiguous residues in length~~, and the monoclonal antibody that binds to the extracellular domain (ECD) of HER-2.

Claim 40. The pharmaceutical composition of claim 18, wherein the agent is the isolated polypeptide comprising ~~an~~ the amino acid sequence selected from the group consisting of SEQ ID NOS: 15, and 29-38, and the fragments thereof ~~of about 80-419 contiguous residues in length~~.

Claim 41. The pharmaceutical composition of claim 18, wherein the agent is the combination of the isolated polypeptide comprising the amino acid sequence selected from the group consisting of SEQ ID NOS: 15, and 29-38, and the fragments thereof ~~of about 80-419 contiguous residues in length~~, and the monoclonal antibody that binds to the extracellular domain (ECD) of HER-2.

The following is an examiner's statement of reasons for allowance: The rejection of claims 1, 2, 18, 42 and 43 under 35 USC 112, first paragraph, as failing to comply with the written description requirement, is withdrawn upon further consideration, in light of applicants' persuasive arguments with respect to *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196

(CCPA 1977), and because Table 1 of the specification teaches the precise variant residues present in the claimed polypeptides and fragments thereof.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private

PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran

Patent Examiner

June 25, 2009

/Alana M. Harris, Ph.D./

Primary Examiner, Art Unit 1643